K002398

NOV - 3 2000



## Section L

## 510(k) Summary of Safety and Effectiveness (2 copies)

**Company:**
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

**Contact:**
Edwin O. Billips
Senior Regulatory Associate
Telephone: 513- 337-7162
Fax: 513- 337-7134

**Date Prepared:**
August 3, 2000

**Modified Devices:**
ENDOPATH® ETS45 Linear Cutters, Linear Staplers and Reloads

**Marketed Devices:**
ENDOPATH® ETS45 Linear Cutters, Linear Staplers and Reloads

**Device Description:**
The ENDOPATH® ETS45 Linear Cutters, Linear Staplers and Reloads are sterile, single patient use instruments that deliver two or three double-staggered rows of staples.

**Indication For Use:**
The ENDOPATH® ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact- Flex45 Articulating Linear Cutter are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

The ENDOPATH® ETS Flex45 No-Knife Articulating Linear Staplers and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and

pediatric procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

**Technological characteristics:**
The technological characteristics of the modified devices are the similar to the marketed products. The modified devices are linear cutters/staplers that are used for transection, resection, and/or creation of anastomoses.

**Performance Data:**
Preclinical testing was performed to ensure that the devices performed as intended. Testing demonstrated satisfactory performance in transection, resection, and/or creation of anastomoses. The modified device will provide increased clamping force when the anvil and channel (which holds the cartridge) is clamped down across tissue, resulting in more consistent staple formation.

**Conclusion:**
Based on 21CFR § 807, we conclude that the modified products are as safe and effective as the marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Mr. Edwin O. Billips
Senior Associate, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K002398
Trade Name: Endopath ETS45 Endoscopic Linear cutters; Flex 45 Endoscopic Articulating Linear cutters; ETS Compact-Flex 45 Articulating Linear cutter; ETS Flex 45 No-Knife Articulating Linear staplers, and ETS Compact-Flex 45 No-Knife Articulating Linear staplers
Regulatory Class: II
Product Code: KOG
Dated: August 3, 2000
Received: August 7, 2000

Dear Mr. Billips:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002398



510(k) Number (if known): K002398

Device Name: **ENDOPATH® ETS45 Linear Cutters, Staplers and Reloads Product Family**

Indications For Use:

The ENDOPATH® ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact- Flex45 Articulating Linear Cutter are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

The ENDOPATH® ETS Flex45 No-Knife Articulating Linear Staplers and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002398

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)